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From analog to digital biomarkers in diagnostics

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As a rule the modern *in-vitro* diagnostics methods make use of the analog system of registration, in which the level of biomarker in blood generally represents the analog signal. The analog system is based on the continuous measurement of the amplitude of electrical signal (although the output is presented in a digital form in most modern equipment). The origin of the electrical signal can be different characteristics of the sample, e.g. spectral, chemical and fluorescent, indirectly relevant to the concentration of the biomarker. The digital diagnostic systems, which respond yes or no, are rarely used in clinics, with an exception of the analysis of disease-associated SNPs. The advantage of the digital approach is the robustness to the statistical noise. The noise comes from the defects in sample acquisition, storage and preparation, imprecision of measurements, differences between individuals (ages, sex, environment, life style, different diseases) and also individual changes over time. Technically the A/D converter transforms of the continuous signal from analog to digital form. The conversion is accomplished by quantization of the analogous input to remove the noise. Regarding the biomedical diagnostics the linear conversion can be performed using the "6-sigma" rule for noise reduction (see Fig. 1). Two groups of signals are processed: first is the healthy group (shaded area), while the second is a random group. Using a limited number of healthy cases the mean signal M0 and its standard deviation σ0. The 99.9% healthy range expressed as M0±3σ0. For the second group of randomly sampled individuals we obtain the range M1±3σ1. In such approach the signals within the healthy range (M0±3σ0) are taken as "0", whilst signals above M1+3σ1 or beneath M1-3σ1 are taken as "1", indicating the disease. At such extremely stringent criteria most of the signals fall into the noise area modulated by nearly random noise factors and thus are neglected. The loss of the signals can be recouped by using the "omics" biomarkers. Multitude of the parameters measured in proteomics and metabolomics can be a substrate for selecting the digital biomarkers complying with the "6-sigma" rule.

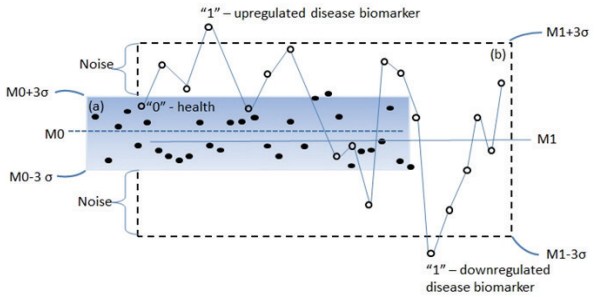

Fig: "6-sigma" rule in biomedical digital diagnostics. Groups: (a) healthy individuals: shaded area and filled circles; (b) Random population unfilled area: empty circles within M1±3σ correspond to the noise, excepting those within M0±3σ, which correspond to health; empty circles outside M1±3σ – correspond to the disease. All the rest empty circles represent noise.

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